PATENT
Attorney Docket No: STK-081
(7557/65)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:	Chubinskaya et al.		
SERIAL NO.:	10/081,163	GROUP NO.:	1645
FILED:	February 20, 2002	EXAMINER:	Not yet assigned
TITLE:	METHODS OF USING BONE MORPHOGENIC PROTEINS AS BIOMARKERS FOR DETERMINING CARTILAGE DEGENERATION AND AGING		

CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8

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Shayna Fischer

Commissioner for Patents
Washington, D.C. 20231

Sir:

Submitted herewith is/are:

Transmittal Form (1 pg.);
Information Disclosure Statement (2 pgs.);
PTO-1449 (6 pgs.);
Cited Art: A1-A2 and C1-C76,
Certificate of First Class Mailing Under 37 C.F.R. 1.8 (1 pg.); and
A Return Postcard Reciept.

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TRANSMITTAL FORM

Application Serial Number	10/081,163
Filing Date	February 20, 2002
First Named Inventor	Chubinskaya
Group Art Unit	1645
Examiner Name	Not yet assigned
Attorney Docket No.	STK-081
Patent No.	Not applicable
Issue Date	Not applicable

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Check Attached
  - ☐ Copy of Fee Transmittal Form
- ☐ Amendment and Response
  - ☐ Second Preliminary
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
  - ☐ Letter to Official Draftsperson including Drawings [Total Sheets _____]
- ☐ Petition for Extension of Time
- ☒ Information Disclosure Statement
  - ☒ Form PTO-1449
  - ☒ Copies of IDS Citations (A1-A2 and C1-C76)
- ☐ Certified Copy of Priority Document(s)
- ☐ Sequence Listing submission
  - ☐ Paper Copy/CD
  - ☐ Computer Readable Copy
  - ☐ Statement verifying identity of above
- ☐ Copy of Notice to File Missing Parts of Application (PTO-1553)
- ☐ Formal Drawing: (__ Sheets)
- ☐ Request For Continued Examination (RCE) Transmittal
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- ☐ Request for Certificate of Correction
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- ☐ Appeal Brief (in triplicate)
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- ☐ Certificate of Facsimile Transmission under 37 C.F.R. 1.8
- ☐ Additional Enclosure(s) *(please identify below)*

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Respectfully submitted,

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2396441

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:	Chubinskaya et al.	
SERIAL NO.:	10/081,163	GROUP NO.: 1645
FILED:	February 20, 2002	EXAMINER: Not yet assigned
TITLE:	METHODS OF USING BONE MORPHOGENIC PROTEINS AS BIOMARKERS FOR DETERMINING CARTILAGE DEGENERATION AND AGING	

Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

☒ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or

☐ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and

☐ the requisite Statement is below, **OR**

☐ the requisite fee under 37 C.F.R. 1.17(p), namely **$180.00**, is included herein, or

☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee, AND**

☐ the requisite Statement is below, **AND**

☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

STATEMENT

As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that **[check the appropriate space only if either (2) or (3) is checked on the previous page and the Statement is required]**:

☐ 1. Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or

☐ 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any individual** designated in 37 C.F.R. 1.56(c) **more than three months** prior to the filing of the Information Disclosure Statement.

Respectfully submitted,

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FORM PTO – 1449	ATTORNEY DOCKET NO.: STK-081
INFORMATION DISCLOSURE STATEMENT	APPLICANTS: Chubinskaya et al.
	SERIAL NO.: 10/081,163
	FILING DATE: February 20, 2002
	GROUP: 1645

U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A1	5,468,845	11/21/95	Oppermann et al.	530	387.9	11/1/93
	A2	5,834,179	11/10/98	Jones et al.	435	4	6/2/95

FOREIGN PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)

OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.		OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
	C1	Aberg, T. et al. "Expression Patterns of Bone Morphogenetic Proteins (BMPs) in the Developing Mouse Tooth Suggest Roles in Morphogenesis and Cell Differentiation", Dev. Dyn. 210(4):383-396 (1997).
	C2	Almanzar, M. et al. "Osteogenic Protein-1 mRNA Expression is Selectively Modulated after Acute Ischemic Renal Injury", J. Am. Soc. Nephrol. 9(8):1456-1463 (1998).
	C3	Anderson, H.C. et al. "Bone Morphogenetic Protein (BMP) Localization in Developing Human and Rat Growth Plate, Metaphysics, Epiphysis, and Articular Cartilage", J. Histochem. Cytochem. 48(11):1493-1502 (2000).
	C4	Arora, K. et al. "BMP Signaling in Drosophila Embryogenesis", Molecular and Developmental Biology of Cartilage (de Crombrugghe et al. Eds.), Ann. NY Acad. Sci. Vol. 785, 80-97 (1996).
	C5	Avner, E.D. et al. "OP-1 is an Inhibitor of Growth and Differentiation in the Developing of Metanephros", J. Am. Soc-Nephrol. 4(3):461 (1993).
	C6	Celeste, A.J. et al. "Identification of Transforming Growth Factor-beta Family Members Present in Bone-Inductive Protein Purified from Bovine Bone", Proc. Natl. Acad. Sci. (USA) 87(24):9843-9847 (1990).
	C7	Chen, M.Y. et al. "Expression of Bone Morphogenetic Protein 7 in Murine Epididymis is Developmentally Regulated", Bio. Reprod. 60(6):1503-1508 (1999).
	C8	Chubinskaya et al. "Endogenous Expression and Processing of Osteogenic Protein-1 in Normal and Osteoarthritic Cartilage", Abstract, 4th Pan-Pacific Connective Tissue Societies Symposium, (November 15-19, 1999).
	C9	Chubinskaya et al. "Endogenous Osteogenic Protein-1 is a Cartilage Repair Factor", OARSI, Fifth World Congress on Osteoarthritis: Barcelona, Spain (October 4-7, 2000).
	C10	Chubinskaya et al. "Exogenous and Endogenous OP-1 in Articular Cartilage", Book Chapter in the BMP Book (S. Lindholm, ed.) (2000).

FORM PTO – 1449 INFORMATION DISCLOSURE STATEMENT	ATTORNEY DOCKET NO.: STK-081 APPLICANTS: Chubinskaya et al. SERIAL NO.: 10/081,163 FILING DATE: February 20, 2002 GROUP: 1645

	C11	Chubinskaya et al. "Human Articular Chondrocytes Express Osteogenic Protein-1", J. Histochem. Cytochem. 48(2):239-250 (2000).
	C12	Chubinskaya et al. "Osteogenic Protein-1 is a Repair Factor that is Endogenously Expressed in Human Articular Cartilage", 4th International OP-1 Conference, Whistler, BC, Canada (March 23-25, 2001).
	C13	Chubinskaya et al. "Osteogenic Protein-1 is a Chondroprotective Factor Endogenously Expressed by Human Articular Chondrocytes", 3rd Symposium – Cartilage and Cartilage Repair in the New Millennium, Gothenburg, Sweden, (April 27-29, 2000).
	C14	Dudley, A.T. et al. "A Requirement for Bone Morphogenetic Protein-7 during Development of the Mammalian Kidney and Eye", Genes Dev. 9(22):2795-2807 (1995).
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	C16	Duneas, N. et al. "Transforming Growth Factor-beta 1: Induction of Bone Morphogenetic Protein Genes Expression during Endochondral Bone Formation in the Baboon, and Synergistic Interaction with osteogenic protein-1", Growth Fact. 15(4):259-277 (1998).
	C17	Ekblom, P. "Genetics of Kidney Development", Curr. Opin. Neph. Hyperten. 5(3):282-287 (1996).
	C18	Francis-West, P. et al. "Signaling Interactions during Facial Development", Mech. Dev. 75:3-28 (1998).
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	C20	Godin, R.E. et al. "Regulation of BMP7 Expression during Kidney Development", Development 125(17):3473-3482 (1998).
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	C22	Heikinheimo, K. et al. "Activin and Bone Morphogenetic Protein (BMP) Signaling during Tooth Development", Eur. J. Oral Sci. 106(1):167-173 (1998).
	C23	Helder, M.N. et al. "Bone Morphogenetic Protein-7 (Osteogenic Protein-1, OP-1) and Tooth Development", J. Dent. Res. 77(4):545-554 (1998).
	C24	Helder, M.N. et al. "Expression Pattern of Osteogenic Protein-1 (Bone Morphogenetic Protein-7) in Human and Mouse Development", J. Histochem. Cytochem. 43(10):1035-1044 (1995).
	C25	Helder, M. et al. "Coordinate Expression of Osteogenic Protein-1 (Bone Morphogenetic Protein-7) and Bone Morphogenetic Protein-3 (Osteogenin) during Mouse and Human-Development", J. Bone and Mineral Res. 8(1):S316 (1993).
	C26	Hofmann, C. et al. "Analysis of Limb Patterning in BMP-7-Deficient Mice", Dev. Genetics 19(1):43-50 (1996).

EXAMINER	DATE CONSIDERED

FORM PTO – 1449 INFORMATION DISCLOSURE STATEMENT	ATTORNEY DOCKET NO.: STK-081 APPLICANTS: Chubinskaya et al. SERIAL NO.: 10/081,163 FILING DATE: February 20, 2002 GROUP: 1645

	C27	Hogan, B.L.M. "Bone Morphogenetic Proteins: Multifunctional Regulators of Vertebrate Development", Genes Dev. 10:1580-1594 (1996).
	C28	Jena, N. et al. "BMP-7 Null Mutation in Mice: Developmental Defects in Skeleton, Kidney, and Eye", Exp. Cell Res. 230(1):28-37 (1997).
	C29	Jeppsson, C. et al. "OP-1 for Cervical Spine Fusion: Bridging Bone in Only 1 of 4 Rheumatoid Patients but Prednisolone did not Inhibit Bone Induction in Rats", Acta. Orthop. Scand. 70(6):559-563 (1999).
	C30	Karsenty, G. et al. "BMP-7 is Required for Nephrogenesis, Eye Development, and Skeletal Patterning", Ann. NY Acad. Sci. 785:98-107 (1996).
	C31	Katagiri, T. et al. "Skeletal Abnormalities in Doubly Heterozygous BMP4 and BMP7 Mice", Dev. Genet. 22(4):340-348 (1998).
	C32	Kim, R.Y. et al. "Bmp6 and Bmp7 are Required for Cushion Formation and Septation in the Developing Mouse Heart", Dev. Bio. 235:449-466 (2001).
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	C34	Kingsley, D.M. "What Do BMPs Do in Mammals – Clues From the Mouse Short-Ear Mutation", Trends in Genet. 10(1):16-21 (1994).
	C35	Lechner, M.S. et al. "The Molecular Basis of Embryonic Kidney Development", Mech. Dev. 62(2):105-120 (1997).
	C36	Lyons, K.M. et al. "Colocalization of BMP-7 and BMP-2 RNAs Suggests that these Factors Cooperatively Mediate Tissue Interactions During Murine Development" Mech. Dev. 50(1):71-83 (1995).
	C37	Lyons, K.M. et al. "The DVR Gene Family in Embryonic Development", Trends Genet. 7(11-12):408-412 (1991).
	C38	Macias, D. et al. "Role of BMP-2 and OP-1 (BMP-7) in Programmed Cell Death and Skeletogenesis During Chick Limb Development" *Development* 124(6):1109-1117 (1997).
	C39	Merrihew et al. "Osteogenic Protein-1 and its Receptors Could be a Chondroprotective Factor in Human Articular Cartilage", 3rd International Conference on Bone Morphogenetic Proteins, p. 92, Lake Tahoe, (June 7-11, 2000).
	C40	Merrihew et al. "Age-Related Changes in Endogenous Osteogenic Protein-1 in Human Knee Articular Cartilage", Orthopedic Research Society Meeting, San Francisco, USA, (February 2001).
	C41	Mintzer, K.A. et al. "*lost-a-fin* Encodes a Type 1 BMP Receptor, Alk8, Acting Maternally and Zygotically in Dorsoventral Pattern Formation", Development 128:859-869 (2001).
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	C43	Nakashima, M. et al. "Transforming Growth Factor-beta Superfamily Members Expressed in Rat Incisor Pulp", Arch. Oral Biol. 43(9):745-751 (1998).
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	C45	Özkaynak, E. et al. "Murine Osteogenic Protein (OP-1): High Levels of mRNA in Kidney", Biochem. Biophys. Res. Comm. 179(1):116-123 (1991).
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	C47	Özkaynak, E. et al. "Osteogenic Protein-2: a New Member of the Transforming Growth Factor-beta Superfamily Expressed Early in Embryogenesis", J. Biol. Chem. 267(35):25220-25227 (1992).
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	C49	Peterkova, R. et al. "Bone morphogenetic proteins (BMPs) and Tooth Development", Trends in Glycosci. Glycoth. 9(47):253-265 (1997).
	C50	Rauch, F. et al. "Temporal and Spatial Expression of Bone Morphogenetic Protein-2, -4, and –7 During Distraction Osteogenesis in Rabbits", Bone 26(6):611-617 (2000).
	C51	Ray, R.P. et al. "Twisted Perspective: New Insights Into Extracellular Modulation of BMP Signaling During Development", Cell 104:801-804 (2001).
	C52	Ripamonti, U. et al. "Bone Morphogenetic Proteins: from Developmental Biology to Molecular Therapeutics", South African J. Sci. 91(6):277-280 (1995).
	C53	Roelen, B.A.J. et al. "Differential Expression of BMP Receptors in Early Mouse Development", Int. J. Dev. Biol. 41(4):541-549 (1997).
	C54	Sampath, T K, "Role of Osteogenic Protein-1 (OP-1) in Growth, Development and Repair of Bone", J. Cell. Biochem. S17e:107 (1993).
	C55	Sato, M. et al. "Mechanical Tension-Stress Induces Expression of Bone Morphogenetic Protein (BMP)-2 and BMP-4, but Not BMP-6, BMP-7, and GDF-5 mRNA, During Distraction Osteogenesis", J. Bone Min. Res. 14(7):1084-1095 (1999).
	C56	Solursh, M. et al. "Osteogenic Protein-1 is Required for Mammalian Eye Development", Biochem. Biophys. Res. Comm. 218(2):438-443 (1996).
	C57	Suzuki, A. et al. "Differential Expression of *Xenopus* BMPs in Early Embryos and Tissues", Zoolog. Sci. (Japan) 10(1):175-178 (1993).
	C58	Thesleff, I. et al. "The Enamel Knot: A Putative Signaling Center Regulating Tooth Development", Cold Spring Harb. Symp. Quant. Biol. 62:257-67 (1997).
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EXAMINER	DATE CONSIDERED

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	C60	Thomas, R. et al. "Androgen-Dependent Gene Expression of Bone Morphogenetic Protein 7 in Mouse Prostate", Prostate 37(4):236-245 (1998).
	C61	Toyono, T. et al. "Temporal Changes in Expression of Transforming Growth Factor-beta Superfamily Members and Their Receptors during Bovine Preodontoblast Differentiation in vitro", Arch. Oral Biol. 42(7):481-488 (1997).
	C62	Toyono, T. et al. "Expression of TGF-beta Superfamily Receptors in Dental Pulp", J. Dent. Res. 76(N9):1555-1560 (1997).
	C63	Vainio, S. et al. "Inductive Tissue Interactions, Cell Signaling, and the Control of Kidney Organogenesis", Cell 90:975-978 (1997).
	C64	Valecillos, M. E. F., "Immunolocalization Of Osteogenic Protein (OP-1) In Developing Murine Teeth", Joint Meeting of the International Assoc. For Dental Res., The American Assoc. Of Dental Res. and the Canadian Assoc. of Dental Res., Chicago, IL, USA, J. Dent. Res. 72 (Abstr. Spec. Issue):110 (March 10-14, 1993).
	C65	Vukicevic, S. et al. "Localization of Osteogenic Protein-1 (Bone Morphogenetic Protein-7) During Human Embryonic Development: High Affinity Binding to Basement Membranes", Biochem. Biophys. Res. Commun. 198(2):693-700 (1994).
	C66	Vukicevic, S. et al. "Localization of the Osteogenic Protein-1 During Early Human Embryonic Development", Fourth Workshop On Cells And Cytokines In Bone And Cartilage, Davos, Switzerland, Calcif. Tissue Int. 50(Suppl. 1):A31 (January 11-14, 1992).
	C67	Vukicevic, S., "Synthesis and Function of Osteogenic Protein-1 (BMP-7) and Bone Morphogenetic Protein-3 (Osteogenin)", Bone Research Branch, National Institute of Dental Research, NIH, Bethesda, MD School of Medicine, University of Zagreb, Croatia (publication date unknown).
	C68	Wall, N.A. et al. "Expression of Bone Morphogenetic Protein-4 (BMP-4), Bone Morphogenetic Protein-7 (BMP-7), Fibroblast Growth Factor-8 (FGF-8) and Sonic Hedgehog (SHH) During Bronchial Arch Development in the Chick", Mech. Dev. 53(3):383-392 (1995).
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	C70	Woolf, A.S. et al. "Roles of Growth Factors in Renal Development", Curr. Opin. Neph. Hyperten. 6(1):10-14 (1997).
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	C72	Wozney, J.M. et al. "Growth Factors Influencing Bone Development", J. Cell Sci. Suppl. 13:149-156 (1990).
	C73	Yamamoto, T. "Immunohistochemical Localization of Bone Morphogenetic Proteins and Their Receptors in Rat and Human Articular Cartilage", Med. J. Kagoshima Univ. 50(4):123-131 (1999).

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	C74	Yazaki, J. "Immunohistochemical Localization of Bone Morphogenetic Proteins and the Receptors in Epiphyseal Growth Plate", Anticancer Res. 18(4A):2339-2344 (1998).
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	C76	You, L. et al. "Bone Morphogenetic Proteins and Growth and Differentiation Factors in the Human Cornea", IOVS 40(2):296-311 (1999).

EXAMINER	DATE CONSIDERED

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